

SENATE BILL 412

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J1

1998 Regular Session
(8lr2283)

ENROLLED BILL

-- Economic and Environmental Affairs/Environmental Matters --

Introduced by **Senator Bromwell**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this
____ day of _____ at _____ o'clock, ____ M.

President.

CHAPTER _____

1 AN ACT concerning

2 **Consumer Protection - Drug Storage and Shipment Safety Act**

3 FOR the purpose of ~~authorizing the State Board of Pharmacy to adopt certain~~
4 ~~regulations concerning the delivery by certain means into the State of~~
5 ~~prescription drug orders to patients or their agents at certain places; requiring~~
6 ~~certain distribution permit holders to maintain adequate storage or shipment~~
7 ~~containers, including proper packaging materials, for certain purposes and~~
8 ~~requiring certain pharmacies for which a pharmacy permit has been issued~~
9 requiring pharmacy permit holders to place certain notices into certain
10 shipments of prescription drugs; and generally relating to the ~~authority of the~~
11 ~~State Board of Pharmacy concerning the delivery and~~ delivery and shipment of
12 certain drugs into the State.

13 BY repealing and reenacting, with amendments,
14 Article - Health Occupations
15 Section ~~42-602~~ 12-403(b)(15) and (16) and (f)(7) and (8)
16 Annotated Code of Maryland

1 (1994 Replacement Volume and 1997 Supplement)

2 BY adding to

3 Article - Health Occupations

4 Section 12-403(b)(17) and (f)(9)

5 Annotated Code of Maryland

6 (1994 Replacement Volume and 1997 Supplement)

7 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
8 MARYLAND, That the Laws of Maryland read as follows:

9 **Article - Health Occupations**

10 ~~12-602.~~

11 (a) (1) ~~In this section, the following words have the meanings indicated.~~

12 (2) ~~"Distribution permit" means a permit issued by the Board under this~~
13 ~~section to distribute prescription drugs or devices into, out of, or within the State as a~~
14 ~~distributor, jobber, manufacturer, or wholesaler, wherever located.~~

15 (3) ~~"Prescription drugs or devices" means any drug or device that,~~
16 ~~because of its toxicity or other potential for harmful effect, the method of its use, or~~
17 ~~the collateral measures necessary for its use, is required by federal law to bear a~~
18 ~~cautionary label warning against dispensing without a prescription or is designated~~
19 ~~by the Department as not safe for use except under the supervision of a practitioner~~
20 ~~licensed to administer drugs or devices of this nature.~~

21 (b) ~~This section does not affect any person while distributing:~~

22 (1) ~~Feed for livestock or poultry;~~

23 (2) ~~Fertilizers;~~

24 (3) ~~Fungicides;~~

25 (4) ~~Insecticide;~~

26 (5) ~~Land plaster;~~

27 (6) ~~Lime;~~

28 (7) ~~Seeds; or~~

29 (8) ~~Devices, drugs, or supplies of any kind for the treatment, care, or cure~~
30 ~~of farm animals.~~

31 (c) ~~A person shall hold a distribution permit issued by the Board before the~~
32 ~~person may distribute prescription drugs or devices as a distributor, jobber,~~
33 ~~manufacturer, or wholesaler.~~

- 1 (d) To qualify for a distribution permit, an applicant shall:
- 2 (1) Satisfy the Board that the applicant will distribute prescription
3 drugs or devices in compliance with the restrictions specified in subsection (c) of this
4 section; and
- 5 (2) Comply with any pertinent regulations adopted under subsection (i)
6 of this section.
- 7 (e) A distribution permit holder may distribute prescription drugs or devices
8 only:
- 9 (1) To the following persons:
- 10 (i) An authorized prescriber;
- 11 (ii) A pharmacy permit holder;
- 12 (iii) A distribution permit holder; or
- 13 (iv) Any other person approved by the Board; and
- 14 (2) In compliance with any rules and regulations adopted under this
15 section.
- 16 (f) To apply for a distribution permit, an applicant shall:
- 17 (1) Submit an application to the Board on the form that the Board
18 provides; and
- 19 (2) Pay to the Board an application fee set by the Board.
- 20 (g) The Board shall issue a distribution permit to any applicant who meets the
21 requirements of this section.
- 22 (h) A distribution permit issued under this section authorizes the distribution
23 permit holder to distribute prescription drugs or devices as a distributor, jobber,
24 manufacturer, or wholesaler while the distribution permit is effective.
- 25 (i) To protect the public health and safety, the Board may adopt rules and
26 regulations regarding the distribution of prescription drugs or devices including
27 regulations regarding:
- 28 (1) Qualifications and information required from an applicant seeking
29 issuance or renewal of a distribution permit;
- 30 (2) Minimum requirements for the receipt, storage, and handling of
31 prescription drugs or devices, security precautions, quality control, recordkeeping,
32 and establishment of written procedures, policy, and responsibilities of personnel;

1 (3) The education and experience of personnel employed in positions
2 responsible for duties referenced in paragraph (2) of this subsection and generally
3 responsible for carrying out those duties that are subject to State licensure
4 requirements under this subtitle; [and]

5 (4) Disciplinary action to be taken against a permit holder who is
6 convicted of or pleads guilty or nolo contendere to a violation of State, federal, or local
7 drug laws or who violates regulations promulgated by the Board under this section;
8 AND

9 (5) ~~WITH REGARD TO A PRESCRIPTION DRUG ORDER THAT IS
10 DELIVERED IN THIS STATE BY THE UNITED STATES MAIL, A COMMON CARRIER, OR A
11 DELIVERY SERVICE TO A PATIENT OR TO THE AGENT OF THE PATIENT, AT THE
12 RESIDENCE OF THE PATIENT OR AT ANOTHER LOCATION DESIGNATED BY THE
13 PATIENT, THE OBLIGATION OF A DISTRIBUTION PERMIT HOLDER TO:~~

14 ~~(I) MAINTAIN ADEQUATE STORAGE OR SHIPMENT CONTAINERS TO
15 ENSURE DRUG STABILITY AND POTENCY, INCLUDING THE USE OF PROPER
16 PACKAGING MATERIALS TO ENSURE THAT THROUGHOUT THE DELIVERY PROCESS
17 THE PRESCRIPTION DRUG IS MAINTAINED AT A STORAGE TEMPERATURE AS
18 DEFINED IN THE GENERAL NOTICES SECTION OF THE UNITED STATES
19 PHARMACOPEIA FOR RECOMMENDED CONDITIONS COMMONLY SPECIFIED ON
20 PRODUCT LABELS;~~

21 ~~(II) PROVIDE A GENERAL WRITTEN NOTICE, TO BE PLACED INTO
22 EACH SHIPMENT OF A PRESCRIPTION DRUG, WHICH ALERTS CONSUMERS THAT
23 UNDER CERTAIN CIRCUMSTANCES CHEMICAL DEGRADATION OF THE PRESCRIPTION
24 DRUG MAY OCCUR;~~

25 ~~(III) PROVIDE A SPECIFIC WRITTEN NOTICE, TO BE PLACED INTO
26 EACH SHIPMENT OF A PRESCRIPTION DRUG, WHICH CONTAINS AN INDIVIDUAL DRUG
27 SENSORY WARNING THAT IDENTIFIES INDICATORS OF A CHEMICAL DEGRADATION
28 OF THE PRESCRIPTION DRUG BEING SHIPPED; AND~~

29 ~~(IV) PROVIDE A WRITTEN NOTICE, TO BE PLACED INTO EACH
30 SHIPMENT OF A PRESCRIPTION DRUG, WHICH PROVIDES A TOLL FREE CONSUMER
31 ACCESS TELEPHONE NUMBER DEDICATED SOLELY TO ANSWERING QUESTIONS
32 FROM CONSUMERS ABOUT THE CHEMICAL DEGRADATION OF PRESCRIPTION DRUGS.~~

33 ~~(j) (1) A distribution permit expires on the December 31 after its effective
34 date, unless the distribution permit is renewed for a 1 year term as provided in this
35 subsection.~~

36 ~~(2) At least 1 month before a distribution permit expires, the Board shall
37 send to the distribution permit holder, by first class mail to the last known address of
38 the distribution permit holder, a renewal notice that contains a statement of:~~

39 ~~(i) The date on which the current distribution permit expires;~~

1 (ii) The date by which the renewal application must be received by
2 the Board for the renewal to be issued and mailed before the distribution permit
3 expires; and

4 (iii) The amount of the renewal fee.

5 (3) Before a distribution permit expires, a distribution permit holder
6 periodically may renew it for an additional 1-year term, if the distribution permit
7 holder:

8 (i) Otherwise is entitled to a distribution permit;

9 (ii) Pays to the Board a renewal fee set by the Board; and

10 (iii) Submits to the Board a renewal application on the form that the
11 Board requires.

12 (4) The Board shall renew the distribution permit of each distribution
13 permit holder who meets the requirements of this section and any regulation adopted
14 under this section.

15 (k) Each distribution permit shall be displayed conspicuously in the place for
16 which it is issued.

17 (l) A distribution permit is not transferable.

18 (m) Subject to any other restriction provided by law, a person may not
19 purchase or obtain any prescription drugs or devices unless the drug or device is
20 obtained from a distribution permit holder, a licensed pharmacist, or an authorized
21 prescriber.

22 (n) A person may not violate any rule or regulation adopted under this section.

23 (o) A distribution permit is void on conviction of the distribution permit holder
24 for any violation of:

25 (1) This section; or

26 (2) Any rule or regulation adopted by the Board under this section.

27 12-403.

28 (b) Except as otherwise provided in this section, a pharmacy for which a
29 pharmacy permit has been issued under this title:

30 (1) Shall be operated in compliance with the law and with the rules and
31 regulations of the Board;

32 (2) Shall be located and equipped so that the pharmacy may be operated
33 without endangering the public health or safety;

1 ~~(3) Shall ensure that a licensed pharmacist be immediately available on~~
2 ~~the premises to provide pharmacy services at all times the pharmacy is in operation;~~

3 ~~(4) Shall be supervised by a licensed pharmacist who is responsible for~~
4 ~~the operations of the pharmacy at all times the pharmacy is in operation;~~

5 ~~(5) Shall provide complete pharmaceutical service by preparing and~~
6 ~~dispensing all prescriptions that reasonably may be expected of a pharmacist;~~

7 ~~(6) Shall provide services to the general public and may not restrict or~~
8 ~~limit its services to any group of individuals unless granted a waiver from this~~
9 ~~requirement by the Board;~~

10 ~~(7) May not offer pharmaceutical services under any term or condition~~
11 ~~that tends to interfere with or impair the free and complete exercise of professional~~
12 ~~pharmaceutical judgment or skill;~~

13 ~~(8) May not make any agreement that denies a patient a free choice of~~
14 ~~pharmacist or pharmacy services;~~

15 ~~(9) May not participate in any activity that is a ground for Board action~~
16 ~~against a licensed pharmacist under § 12-313 of this title;~~

17 ~~(10) (i) Shall maintain at all times a current reference library that is~~
18 ~~appropriate to meet the needs of:~~

19 ~~1. The practice specialty of that pharmacy; and~~

20 ~~2. The consumers the pharmacy serves; and~~

21 ~~(ii) Shall comply with any regulations adopted by the Board~~
22 ~~establishing the types of texts required to be included in the reference libraries in~~
23 ~~each of the various practice specialty pharmacies;~~

24 ~~(11) (i) Shall maintain at all times the minimum professional and~~
25 ~~technical equipment and sanitary appliances that are necessary in a pharmacy:~~

26 ~~1. To prepare and dispense prescriptions properly; and~~

27 ~~2. To otherwise operate a pharmacy; and~~

28 ~~(ii) Shall:~~

29 ~~1. Be equipped with the minimum equipment and appliances~~
30 ~~specified by the Board under this section; and~~

31 ~~2. Be kept in a clean and orderly manner;~~

32 ~~(12) Shall store all prescription or nonprescription drugs or devices~~
33 ~~properly and safely subject to the rules and regulations adopted by the Board;~~

1 ~~(13)~~ Shall:

2 (i) Make and keep on file for at least 5 years a record of each
3 prescription prepared or dispensed in the pharmacy;

4 (ii) Disclose the records and files maintained of prescriptions for
5 drugs or devices that identify or may be readily associated with the identity of a
6 patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health
7 General Article; and

8 (iii) Keep additional records as required by the rules and
9 regulations adopted by the Board;

10 (14) Except as otherwise provided under federal law, shall establish and
11 maintain mechanisms to ensure that all prescription drugs or devices used within
12 institutions that provide acute, subacute, or long-term care, or within their related
13 corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,
14 subject to rules and regulations adopted by the Board and policies established by the
15 institution;

16 (15) Shall provide such personnel, automation, and technology as are
17 necessary to allow the licensed pharmacist employee sufficient time to utilize the
18 pharmacist's knowledge and training and to perform competently the functions of a
19 licensed pharmacist as required by law; [and]

20 (16) Shall provide such personnel, automation, and technology as are
21 necessary to allow the licensed pharmacist employee to comply with the labeling
22 requirements specified in § 12-505; AND

23 (17) WITH REGARD TO A PRESCRIPTION DRUG THAT IS DELIVERED IN
24 THIS STATE BY THE UNITED STATES MAIL, A COMMON CARRIER, OR A DELIVERY
25 SERVICE ~~WHEN THE DRUG AND IS NOT PERSONALLY HAND DELIVERED DIRECTLY TO~~
26 A PATIENT OR TO THE AGENT OF THE PATIENT, ~~OR AT THE RESIDENCE OF THE~~
27 PATIENT; OR AT A ~~ANOTHER~~ LOCATION DESIGNATED BY THE PATIENT, SHALL:

28 (I) PROVIDE A GENERAL WRITTEN NOTICE TO BE PLACED INTO IN
29 EACH SHIPMENT OF A PRESCRIPTION DRUG; THAT ALERTS ~~THE RECIPIENT A~~
30 CONSUMER THAT, UNDER CERTAIN CIRCUMSTANCES, A MEDICATION'S
31 EFFECTIVENESS MAY BE AFFECTED BY EXPOSURE TO EXTREMES OF HEAT, COLD, OR
32 HUMIDITY; AND

33 (II) PROVIDE A SPECIFIC WRITTEN NOTICE TO BE PLACED INTO IN
34 EACH SHIPMENT OF A PRESCRIPTION DRUG, ~~THAT PROVIDES TO THE RECIPIENT~~
35 THAT PROVIDES A CONSUMER WITH A TOLL-FREE OR LOCAL CONSUMER ACCESS
36 TELEPHONE NUMBER ACCESSIBLE DURING REGULAR HOURS OF OPERATION, ~~THAT~~
37 WHICH IS DESIGNED TO RESPOND TO CONSUMER QUESTIONS PERTAINING TO ~~THE~~
38 EFFECTIVENESS OF A MEDICATION ~~MEDICATIONS.~~

39 (f) A nonresident pharmacy shall:

- 1 (1) ~~Comply with the laws of the state in which it is located;~~
- 2 (2) ~~On an annual basis and within 30 days after a change of office,~~
3 ~~corporate officer, or pharmacist, disclose to the Board the location, names, and titles~~
4 ~~of all principal corporate officers and all pharmacists who are dispensing~~
5 ~~prescriptions for drug or devices to persons in this State;~~
- 6 (3) ~~Comply with all lawful directions and requests for information from~~
7 ~~the regulatory or licensing agency of the state in which it is located and all requests~~
8 ~~for information made by the Board pursuant to this section;~~
- 9 (4) ~~Maintain at all times a valid, unexpired permit to conduct a~~
10 ~~pharmacy in compliance with the laws of the state in which it is located;~~
- 11 (5) ~~Maintain its records of prescription drug or devices dispensed to~~
12 ~~patients in this State so that the records are readily retrievable;~~
- 13 (6) ~~During its regular hours of operation, but not less than 6 days a~~
14 ~~week, and for a minimum of 40 hours per week, provide toll-free telephone service to~~
15 ~~facilitate communication between patients in this State and a pharmacist who has~~
16 ~~access to the patient's prescription records;~~
- 17 (7) ~~Disclose its toll-free telephone number on a label affixed to each~~
18 ~~container of drug or devices; [and]~~
- 19 (8) ~~Comply with the laws of this State relating to the confidentiality of~~
20 ~~prescription records if there are no laws relating to the confidentiality of prescription~~
21 ~~records in the state in which the nonresident pharmacy is located; AND~~
- 22 (9) ~~COMPLY WITH THE REQUIREMENTS OF SUBSECTION (B)(17) OF THIS~~
23 ~~SECTION.~~

24 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
25 October 1, 1998.